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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,866	05/29/2001	Brian Sorrentino	02427/1203347-US2	4688

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,866	SORRENTINO ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,22-24 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 22-24 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/21/06 has been entered.

Claims 16, 22-24 and 29-34 are pending.

Claims 16, 22-24 and 29-34 drawn to an isolated antibody that binds to an extracellular portion of BCRP are under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

5. Claims 16, 22-24 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16, 22-24 and 29-34 are indefinite and ambiguous in the recitation of BCRP protein in the second line. Recitation of a protein without providing SEQ ID NO for the protein is indefinite and ambiguous because different laboratories may have the same name for a different proteins. It is also noted that the instant Specification disclosed that BCRP is referred when said protein is obtained from any mammalian, source but mBCRP or huBCRP when obtained from murine or human respectively (see page 3, lines 25-30 in particular).

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7 . Claims 16, 22-24 and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

" wherein the antibody binds to living MCF-7 or 3T3 cells expressing BCRP on their surface wherein the antibody does not bind to living MCF-7 cells that do not express BCRP on their surface and wherein the antibody does not bind to denaturated BCRP" claimed in claim 16 represent(s) a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come(s) from.

The specification and the claims as originally field only support antibody that recognized an extracellular portion of BCRP, wherein said extracellular portion of the BCRP is in its natural conformation.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

9. Claims 16, 22 and 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,313,277 (IDS)

US Patent' 277 teaches an isolated polyclonal and monoclonal antibody that binds to BCRP (see entire document, column 4, lines 50-60 in particular).

Although the reference is silent about the antibody binding to an extracellular portion of BCRP or does not binds to denaturated BCRP, said functional limitation would be inherent properties of the referenced antibody, because the referenced antibody was obtained against the same

antigen as claimed. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies does not binds to denaturated BCRP as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

It is noted that the instant claims 31-34 recited a process of producing a monoclonal antibody that is different from the referenced monoclonal antibody that binds to BCRP. However, the instant claims are drawn to a product (antibody) and the patentability of the product does not depend on its method of production. In re Thrope,227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

This position is further supported by the recent decision of the court who states "IF APPLICANT HAS DISCLOSED FULLY CHARACTERIZED ANTIGEN, EITHER BY STRUCTURE, FORMULA, CHEMICAL NAME, OR PHYSICAL PROPERTIES, OR BY DEPOSITING PROTEIN IN PUBLIC DEPOSITORY, THEN APPLICANT CAN CLAIM ANIBODY BY ITS BINDING AFFINITY TO THAT DESCRIBED ANTIGEN" Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004). Here, US Patent '277 disclosed a fully characterized BCRP antigen by its structure.

The reference teaching anticipates the claimed invention.

10 . Claims 16, 22-24 and 29-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,485,933.

US Patent' 933 teaches an isolated polyclonal and monoclonal antibody that binds to BCRP (see entire document, Abstract and column 16, lines 15-30 in particular). US Patent' 933 further teaches that said antibody is chimeric or humanized or attached to detectable label (see overlapping columns 18 and 19).

Although the reference is silent about the antibody binding to an extracellular portion of BCRP or does not binds to denaturated BCRP, said functional limitation would be inherent properties of the referenced antibody, because the referenced antibody was obtained against the same antigen as claimed. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies does not binds to denaturated BCRP as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

It is noted that the instant claims 31-34 recited a process of producing a monoclonal antibody that is different from the referenced monoclonal antibody that binds to BCRP.

However, the instant claims are drawn to a product (antibody) and the patentability of the product does not depend on its method of production. In re Thrope,227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

This position is further supported by the recent decision of the court who states "IF APPLICANT HAS DISCLOSED FULLY CHARACTERIZED ANTIGEN, EITHER BY STRUCTURE, FORMULA, CHEMICAL NAME, OR PHYSICAL PROPERTIES, OR BY DEPOSITING PROTEIN IN PUBLIC DEPOSITORY, THEN APPLICANT CAN CLAIM ANIBODY BY ITS BINDING AFFINITY TO THAT DESCRIBED ANTIGEN" Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004). Here, US Patent '933 disclosed a fully characterized BCRP antigen by its structure.

The reference teaching anticipates the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 16, 23, 24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,313,277 in view of Owens (1994).

The teaching of US Patent' 277 has been discussed, supra.

The claimed invention differs from the reference teaching in that US Patent '277 does not explicitly teaches an isolated antibody, wherein said antibody is chimeric, as claimed in claim 23 or humanized as claimed in claim 24 or attached to a detectable label, as claimed in claim 29.

Owens *et al.*, teach the modification of murine antibodies such as a chimeric antibody, a single chain antibody, or a humanized antibody antibodies monoclonal antibody technology, chimeric antibody or attaching antibody to a detectable label. Owens *et al* further teach humanized

antibodies use in therapy of human diseases or disorders, since the human or humanized antibodies are much less likely to induce an immune response. Also, antibody fragments are the reagents of choice for some clinical applications, and the chimeric antibodies offers the ability to mediate antigen-dependent cytotoxicity and complement -dependent cytotoxcity (see the entire document).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to produce the monoclonal antibody taught by US Patent ,277 as chimeric, humanized antibody, taught by the Owens *et al.*

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the humanized antibodies are much less likely to induce an immune response and because the antibody fragments are the reagents of choice for some clinical applications and the chimaeric antibodies offers the ability to mediate antigen-dependent cytotoxicity and complement-dependent cytotoxcity as taught by Owens *et al.*

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expection of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 16 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent 6,313,277 or US Patent 6,485,933 each in view of in view of U.S. Patent No. 4,281,061

The teaching of US Patent 6,313,277 or US Patent 6,485,933 have been discussed, supra.

US Patent 6,313,277 or US Patent 6,485,933 does not teach a kit comprising in suitable container the antibody that binds to BCRP.

US Paten '061 teaches that reagents of the pharmaceutical compositions can be provided as kits as a matter of convenience , optimization and economy of the users (see col 22, line 62 - col 23, line 4 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Paten '061 to those of US Patent '933 or US Patent '277 to obtain a claimed kit comprising the antibody that binds to BCRP.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because assemble the reagents in a kit format a matter of convenience , optimization and economy of the users as taught by US Paten. '061 and the antibody that binds to BCRP as taught by US Patent 6,313,277 or US Patent 6,485,933 can be in a pack or a kit for convenience and economy.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

10/27/06